COVIDIEN

K131614

510(K) SUMMARY

1. 510(k) Owner:

Applicant:	Covidien 15 Hampshire Street Mansfield, MA 02048
Telephone:	(508) 452 – 4135
Fax:	(508) 452 – 4135
Contact:	Daniel Campion
Title:	Associate Director Regulatory Affairs
Date Prepared:	May 31, 2013

AUG 2 9 2013

2. Device:

Trade Name:	Reprocessed ClosureFast Radiofrequency (RF) Catheter
Classification Name:	Electrosurgical Cutting & Coagulation, Reprocessed
Regulation Number:	21 CFR 878.4400
Product Code(s):	NUJ
Classification:	Class II

3. Predicate Device:

The Reprocessed ClosureFast RF Catheter is substantially equivalent in intended use and operation to the predicate ClosureFast RF Catheter (K061373).

4. Device Description:

The Reprocessed ClosureFast RF Catheter relies on the delivery of radiofrequency (RF) energy via an intravascular catheter that delivers temperature controlled heat to a predetermined length of superficial vessel. The ClosureFast RF Catheter is a sterile device with a 7cm radiofrequency heating element, a molded handle with start/stop switch, a flexible shaft and an integrated instrument cable, and is designed for use with the ClosureRFG (RF) Generator.

5. Intended Use:

The Reprocessed ClosureFast RF Catheters are intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

6. Technological Characteristics:

The Reprocessed ClosureFast RF Catheters are identical to the predicate device in design, materials of construction, and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation.

7. Performance Data:

Representative samples of Reprocessed ClosureFast RF Catheters were tested to demonstrate appropriate functional characteristics through bench top verification testing and process validation testing was performed to validate the cleaning process in line with AAMI TIR 30:2011 requirements. The manufacturing process includes visual and validated functional testing of all products produced prior to release.

8. Conclusion:

Covidien concludes that the Reprocessed ClosureFast RF Catheter is safe, effective, and substantially equivalent to the predicate device, ClosureFast RF Catheters K061373, as described in this premarket notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Covidien
Daniel Campion
Associate Director Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

August 29, 2013

Re: K131614
Trade/Device Name: Reprocessed ClosureFast Radiofrequency (RF) Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: July 26, 2013
Received: July 31, 2013

Dear Mr. Campion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known): K131614

Device Name: Reprocessed ClosureFast RF Catheter

Indications for Use:

The Reprocessed ClosureFast RF Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S